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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/500,375

06/02/2005

Giuseppe Sasso

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7553

22852

7590

05/15/2008

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EXAMINER

SOROUGH, ALI

ART UNIT

PAPER NUMBER

1616

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DELIVERY MODE

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/500,375	SASSO ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ALI SOROUGH	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 28 April 2008.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 11-13 and 15-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 11-13 and 15-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## **DETAILED ACTION**

### ***Continued Examination Under 37 CFR 1.114***

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 04/28/2008 has been entered.

### ***Status of the Claims***

Claims 1-10 and 14 have been cancelled and claim 11 has been amended. Therefore, claims 11-13 and 15-20 are currently pending examination for patentability.

Rejections and/or objections not reiterated from the previous Office Action are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set of rejections and/or objections presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

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invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

1. Claims 11-13, 15-18 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5200200, published 04/06/1993).

### **Applicant Claims**

A multiple compartment flexible bag assembly having in one compartment an aqueous sodium bicarbonate solution and in a second compartment an aqueous acid component, comprising: glucose, acid, sodium, potassium, calcium, magnesium, chloride, and dissolved CO<sub>2</sub>.

### ***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

Veech teaches, "The invention lies in the field of methods for the perpetration of therapeutic aqueous solutions which contain dissolved therein at the time of use unstable metabolites of the type normally present in human blood plasma, and also to the field of filled storable containers useful for the storage of such solutions in unit dose forms." (See column 1, Lines 12-18). "Flexible walled containers incorporating plastics and/or metal foil are currently of growing interest in medical environments and the like.

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Heretofore, various plastic containers containing integrally a plurality of chambers have been provided for storage of therapeutic materials. Each chamber holds one or a group of separatable components which are admixed into a common solution by chamber wall rupture internally before solution use.” (See column 1, Lines 60-67). Veech further teaches, “a method for administration of a redox active parenteral therapeutic solution comprising the steps of (A) dissolving in sterile and substantially pyrogen free water inorganic salts and carbon dioxide which are also both sterile and substantially pyrogen free thereby producing an aqueous solution having the following composition:

<b><i>Component</i></b>	<b>Quantity (in mMoles/Liter)</b>
Na <sup>+</sup>	130-165
K <sup>+</sup>	0-5
Ca <sup>++</sup>	0-2.5
Mg <sup>++</sup>	0-1.5
Cl <sup>-</sup>	90-120
HCO <sub>3</sub> <sup>-</sup>	.5-60
CO <sub>2</sub>	.1-25

...” (See claim 1). Veech teaches more specifically a redox active peritoneal dialysis solution prepared as follows: A master batch solution is prepared containing the components below

<b><i>Component</i></b>	<b>Quantity (in mMoles/Liter)</b>
Na <sup>+</sup>	107.9
K <sup>+</sup>	4.5
Ca <sup>++</sup>	1.1
Mg <sup>++</sup>	0.55
Cl <sup>-</sup>	102
l-lactate-	10.7
d-betahydroxybutyrate-	3
CO <sub>2</sub>	1.45
Glucose	277
pH	5.0

(See Column 8, example 2). A uniform particulate mixture comprising: particulate NaHCO<sub>3</sub>, Na acetoacetate, and particulate Na pyruvate is also prepared. (See column 8, Lines 19-22). The charging procedure is the done according to example 1. (See column 8, Line 25). Example 1 teaches that sodium pyruvate is mixed with 1 liter of water and charged (filled) into lower compartment of the container and the compartment is sealed. (See column 7, Lines 36-41). Then the master batch solution is charged into the upper compartment of the container and the compartment is sealed. (See column 7, Lines 41-44). When the tabs separating the two chambers are pulled apart the two solutions intermix providing the desired dialysis solution. (See column 8, Lines 27-31). In regards to the partial pressure value of carbon dioxide, the composition of Veech is the same as the composition of the instant invention. Products of identical chemical

composition cannot have mutually exclusive properties. A chemical composition and its properties are inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.

**Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)**

Although, Veech does not teach that the particulate mixture to be an aqueous solution it would have been obvious to one of ordinary skill in the art at the time of the instant invention that the particulate mixture could be formulated into an aqueous solution prior to being charged into the lower compartment of the container.

Veech teaches that the method by which to charge the two components in the separate compartments should be carried out as described in Example 1 (column 7). In Example 1 Veech teaches a similar master batch solution to be charged into the upper compartment of the container as being prepared in Example 2 and a second particulate component (sodium pyruvate) to be charged into the lower compartment of the container. (See column 7, Lines 20-44). The sodium pyruvate is provided in a one-liter solution of water. (See column 7, Lines 36-38).

**Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)**

It would have been obvious to one of ordinary skill in the art to formulate the particulate mixture comprising sodium bicarbonate into an aqueous solution. One would have been motivated to do this because to do so would provide a “ready for

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conventional intravenous administration" solution (See column 7, Lines 54-55). Further, by providing the particulate mixture comprising sodium bicarbonate in an aqueous solution it would make for a more uniform distribution of the particulates when the two components are mixed for use. Therefore, if a one of ordinary skill in the art wanted to provide a peritoneal solution with increased storage ability and uniform mixing at the time of use one would prepare the two solutions as taught by Veech and place into a multi-compartment bag. Although, Veech does not teach the concentration of carbon dioxide in the aqueous acid solution, such a concentration would have been obvious to one of ordinary skill in the art. One of ordinary skill would have arrived at the instant concentration through routine optimization of the invention of Veech. For the foregoing reasons the instantly claimed invention would have been obvious to one of ordinary skill in the art at the time of the instant invention.

2. Claim 19 is rejected under 35 U.S.C. 103(a) as being unpatentable over Veech (US 5200200, published 04/06/1993) in view of Segers et al. (US 5383324, published 01/24/1995).

#### **Applicant Claims**

A multiple compartment flexible bag assembly having in one compartment an aqueous sodium bicarbonate solution and in a second compartment an aqueous acid component, comprising: glucose, acid, sodium, potassium, calcium, magnesium, chloride, and dissolved CO<sub>2</sub>. Wherein the multiple component flexible bag is over-wrapped in a flexible gas-impermeable plastic material.



***Determination of the Scope and Content of the Prior Art (MPEP §2141.01)***

The teachings of Veech are presented above.

***Ascertainment of the Difference Between Scope the Prior Art and the Claims  
(MPEP §2141.012)***

Veech lacks the teaching of the multiple compartment flexible bags being over-wrapped in a flexible gas-impermeable plastic material. This deficiency is cured by the teachings in Segers et al.

Segers et al. teaches, "The present invention relates generally to peritoneal dialysis. More specifically, the present invention relates to manufacturing and storing bicarbonate peritoneal dialysis solutions." (See column 1, Lines 6-9). "The device includes an exterior body. The exterior body can be made of any rigid or flexible material that is permeable to water and carbon dioxide." (See column 5, Lines 9-11). Segers et al. further teaches, "The overpouch or second container surrounds both the device and the bicarbonate container. The overpouch is made of any material with low permeability to gas and specifically, carbon dioxide. The low permeability of the overpouch prevents CO<sub>2</sub> from escaping ..." (See column 6, Lines 18-23 and Figure 2).

***Finding of Prima Facie Obviousness Rational and Motivation  
(MPEP §2142-2143)***

It would have been obvious to one of ordinary skill in art at the time of the invention to use the overpouch of Segers et al. with the invention of Veech. Both

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patents teach inventions that are to store solutions having carbon dioxide as a component and to be utilized for dialysis purposes. One would be motivated to use the Segers et al.'s overpouch because the plastic containers used by Veech appear to be formed of materials through which carbon dioxide is diffusible. This loss of carbon dioxide leads to the increase in pH of the bicarbonate solution, which leads to the precipitation of calcium carbonate from the solution. The use of the overpouch made of material of low permeability to carbon dioxide would limit the loss of carbon dioxide.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ali Soroush whose telephone number is (571) 272-9925. The examiner can normally be reached on Monday through Thursday 8:30am to 5:00pm E.S.T.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's Supervisor, Johann Richter can be reached on (571) 272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business

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Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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Art Unit: 1616

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